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IN THE

# Supreme Court of the United States

**OCTOBER TERM, 1975**

No. 75-1199

CHRISTIAN J. JANSEN, JR.,
*Petitioner,*

vs.

C. MARSHALL DANN,
COMMISSIONER OF PATENTS AND TRADEMARKS,
*Respondent.*

## PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF CUSTOMS AND PATENT APPEALS

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## PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF CUSTOMS AND PATENT APPEALS

Petitioner, Chirstian J. Jansen, Jr., prays that a writ of certiorari issue to review the judgment of the United States Court of Customs and Patent Appeals entered November 20, 1975, a timely filed petition for rehearing being denied on January 15, 1976.

## REFERENCE TO OPINIONS BELOW

The opinions of the United States Patent and Trademark Office Board of Appeals are not reported but are set forth in Appendix A, *infra* pp. A1-A10. The opinion of the United States Court of Customs and Patent Appeals is reported at 525 F.2d 1059, 187 USPQ 743 (1975) and is set forth in Appendix A, *infra* pp. A11-A17.

## JURISDICTION

The judgment of the United States Court of Customs and Patent Appeals was dated November 20, 1975. A petition for rehearing was filed on December 9, 1975 and was denied on January 15, 1976.

The jurisdiction of this Court is invoked under the provisions of 28 U.S.C. § 1256.

## CONSTITUTIONAL PROVISION AND STATUTE

The Constitutional provision involved is Article 1, Section 8, which reads as follows:

> "The Congress shall have power . . . To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."

The Federal Statute involved is 35 U.S.C. § 103 which reads as follows:*

> "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

## QUESTIONS PRESENTED

1. Whether for a pharmaceutical product the standards of patentability under the Constitution and under 35 U.S.C.

* This same language is retained in proposed patent reform legislation such as Senate Bill S. 2255 which has received approval of the Senate Committee on the Judiciary.

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§ 103 can be applied without consideration of significantly improved results obtained by a novel formulation.

2. Whether rejection of claims in a patent application relating to a pharmaceutical product can be made by the Patent and Trademark Office under 35 U.S.C. § 103 without challenge to applicant's position and evidence that the admittedly novel subject matter of the claims are substantial improvements over the prior art which eliminate risks of needless sickness and death and which reduce the cost of medical care inherent in each and every prior art product.

3. Whether a pharmaceutical product having demonstrably improved safety and which is formulated contrary to the teachings of persons of skill in the art is patentable under the Constitutional and statutory standards.

## STATEMENT OF THE CASE

Christian J. Jansen, Jr. filed for a patent application on a vitamin formulation which preferably included the two vitamins, vitamin $B_{12}$ and folic acid, each in the amount of .5 milligrams. The Patent Office denied a patent to Dr. Jansen based upon the provisions of 35 U.S.C. § 103.

Folic acid (pteroylglutamic acid) and vitamin $B_{12}$ (cyanocobalamin) are both vitamins. Vitamins are nutrients which are needed in small amounts by all individuals throughout their entire lifetime. While a balanced diet will provide normal individuals with enough of each of these two vitamins, it is common practice for persons to take vitamin supplements to insure that they have the vitamins which they need in the event that they do not always eat a balanced diet.

The prior art is replete with vitamin supplement products containing both folic acid and vitamin $B_{12}$. How-

ever, the folic-acid-containing products of the prior art which contain enough folic acid to supply the recommended daily allowance are recognized as having dangers associated with them. The danger lies in the possibility that administration of these folic-acid-containing products to a person who happens also to be deficient in vitamin $B_{12}$ causes masking to occur. Masking is the suppression of the anemic condition which otherwise would result from a vitamin $B_{12}$ deficiency. Thus, the folic acid ameliorates the anemia caused by the vitamin $B_{12}$ deficiency and the person appears cured. Thereafter, however, irreversible neurological damage occurs. The person may suddenly become crippled. The person may die.

Most folic acid containing products also contain small amounts of vitamin $B_{12}$. These small amounts of vitamin $B_{12}$ are enough to insure that a *normal* individual will have sufficient vitamin $B_{12}$ to avoid the problem of masking and to avoid the resultant problem of permanent neurological damage or death. However, a large number of individuals have or develop during their lifetimes a malfunction which prevents effective absorption of the small amounts of vitamin $B_{12}$ which often accompany folic-acid-containing products. These persons are referred to as having pernicious anemia. For these individuals taking the folic-acid-containing products, permanent irreversible neurological damage can still occur even though small amounts of Vitamin $B_{12}$ (.005 to .05 mg.) are present in the folic-acid-containing products. Death can occur. Products containing folic acid in substantial amounts are distributed only as prescription products which are available only with the direction of a physician. Folic-acid-containing products are often accompanied by warning labels warning of the dangers

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* Goodman & Gilman, *The Pharmacological Basis of Therapeutics*, 1440 (4th ed. 1970).

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associated with the product. A medical textbook* makes the following statement:

> "It is therefore incumbent on the physician *never* to prescribe a multi-vitamin preparation containing more than .1 mg. of folic acid per daily dose unless he is reasonably sure that the patient does not have vitamin $B_{12}$ deficiency."

The Food and Drug administration has regulations concerning the labeling with warning labels of preparations containing folic acid and cyanocobalamin. All prior art multi-vitamin products have either an insufficient amount of folic acid to provide the recommended daily allowances or have so much folic acid as to present a danger to those persons who have or may develop difficulties in absorbing vitamin $B_{12}$. The prior art does not offer any safe method or product whereby an individual can receive the amount of folic acid he needs in a vitamin supplement without taking a product which is potentially a dangerous product, requiring a physician's care.

It is at this defect in the prior art products that appellant's invention is directed. Appellant has discovered that if the amount of vitamin $B_{12}$ contained with oral folic-acid-containing products is increased substantially over the amount previously present in oral folic-acid-containing products, that the folic acid can be delivered safely and without any risk of neurological damage or death. Careful clinical studies were run on over 100 individuals to verify the improved safety of Dr. Jansen's preparation. Evidence of this was submitted to the Patent and Trademark Office. Many of the persons participating in the study were known to have pernicious anemia. The novel folic-acid-containing formulation proved to be completely safe and effective even when given to persons who were vitamin $B_{12}$ deficient and who had been proven to have difficulty in absorbing vita-

min $B_{12}$. The presence of large amounts of folic acid in the novel formulation did not result in any neurological damage or death which otherwise would have resulted if a prior art product containing large amounts of folic acid had alone been given.

For the first time a product was formulated which could be given to the general public to provide a safe and inexpensive way to insure that they had the nutrients they needed. For the first time a product was formulated which could be given to the general public to fully and safely prevent vitamin deficiency anemias in the same way that vitamin C is now used to prevent scurvy. Contrary to the situation existing in the prior art, a person taking the novel formulation does not need to first become ill with a vitamin deficiency and thereafter seek the help of a physician. Nor is it necessary with the novel formulation for a person to be tested with difficult, expensive and time consuming tests which would otherwise be necessary to differentiate between vitamin $B_{12}$ deficiency and folic acid deficiency.

Dr. Jansen has been seeking permission from the Food and Drug Administration to market his improved formulation by filing a new drug application. When the FDA learned that the preparation of Dr. Jansen contained large quantities of folic acid, they responded saying that such amount is dangerous and its use should be carefully monitored. Marvin Seife, Acting Director of the Office of Scientific Evaluation of the Bureau of Drugs of the FDA, stated to Dr. Jansen that his views on the safety and efficacy of his proposed product were not shared by the preponderance of contemporary scientific-medical opinion. He went on to quote literature to support his position. Long after Dr. Jansen made his invention and filed for his patent application, companies have continued to manufacture and

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sell folic-acid-containing products which admittedly had either insufficient amounts of folic acid to supply the recommended daily allowances for individuals or admittedly were dangerously formulated to result in possible masking of vitamin $B_{12}$ deficiencies. Nonetheless there is not one person of record, other than Dr. Jansen, who has advocated use of the safe formulation of folic-acid-containing products discovered by Dr. Jansen.

## JURISDICTION OF THE UNITED STATES COURT OF CUSTOMS AND PATENT APPEALS AND THE PATENT AND TRADEMARK OFFICE

The jurisdiction of the United States Court of Customs and Patent Appeals arose under 28 U.S.C. § 1542. The jurisdiction of the Patent and Trademark Office arose under Title 35, Parts I and II, of the United States Code, and more particularly under 35 U.S.C. § 131. Appeal from the decision of the Board of Appeals of the Patent and Trademark Office is provided for additionally by 35 U.S.C. § 141 through § 144. Christian J. Jansen, Jr. filed his application for a patent on July 22, 1970. The appeal to the United States Court of Customs and Patent Appeals was filed on December 11, 1974.

## REASONS FOR ALLOWANCE OF THE WRIT

Title 35, United States Code, section 103 is fundamental to the patent system. This section of title 35 is critically involved in most patent lawsuits and in most patent applications that are filed. It is imperative that the law be as clear as possible with regard to the meaning and interpretation given to section 103. It is believed that the United States Court of Customs and Patent Appeals in deciding the case below has failed to apply the proper standards

in determining whether Dr. Jansen's preparation is patentable. It is believed that the law applied in the present case is inconsistent with the law applied in this Court's decision in *United States v. Adams,* 383 U.S. 39, 148 USPQ 479, (1966).

In the Adams case, this Court held that an invention directed to a combination of ingredients can be patentable even though each of the ingredients had been previously used in the same art. The Court there focused upon the improved results of the novel combination of Adams. Moreover, the response Dr. Jansen received from the Food and Drug Administration and others was not unlike the response Adams received when he first tried to gain approval for his invention, *United States v. Adams,* 383 U.S. at 43, 148 USPQ at 480:

> Less than a month after filing for his patent, Adams brought his discovery to the attention of the Army and Navy. Arrangements were quickly made for demonstrations before the experts of the United States Army Signal Corps. The Signal Corps scientists who observed the demonstrations and who conducted further tests themselves did not believe the battery was workable. Almost a year later, in December 1942, Dr. George Vinal, an eminent government expert with the National Bureau of Standards, still expressed doubts. He felt that Adams was making "unusually large claims" for "high watt hour output per unit weight," and he found "far from convincing" the graphical data submitted by the inventor showing the battery's constant voltage and capacity characteristics. He recommended, "Until the inventor can present more convincing data about the performance of his [battery] cell, I see no reason to consider it further."

The Constitutional standard for patentability is, of course, ultimately determined by this Court. The language of the Constitution authorizes patents to be granted to

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"promote the progress" of the useful arts. It seems elementary that progress in the useful arts can only be determined by comparison of the results obtained with a new formulation to the results obtained with that which had gone before. To analyze an invention in a vacuum without comparison of the results obtained with it to results obtained with products previously marketed is to ignore the one of the most useful measures for determining progress within the useful arts. Christian J. Jansen, Jr. has attempted to have factual determinations made by the Patent and Trademark Office Board of Appeals and by the United States Court of Customs and Patent Appeals relating to results achieved with products marketed prior to Dr. Jansen's invention in comparison to the results achieved through the use of Dr. Jansen's novel preparation. The Board of Appeals in its decision on reconsideration stated as follows (Appendix, *infra* p. A-9):

> "We understand appellant's insistance that a composition containing the specified dosages of vitamin $B_{12}$ and folic acid and that the administration of such dosages 'eliminate needless sickness and death, and reduce the cost of medical care' . . ., despite adverse criticism and condemnation. However, this running controversy between appellant and 'the entire scientific and medical community' . . . does not serve to establish the unobviousness of the claimed subject matter."

The Court of Customs and Patent Appeals completely sidestepped appellant's factual presentation concerning the improved safety of Dr. Jansen's product as compared with the prior art products and stated as follows (Appendix, *infra* p. A-16):

> "Appellant asserts a theory concerning the manner in which the claimed invention and method effectively treat undifferentiated anemia. We express no view on the merit of that theory."

Dr. Jansen's invention is the first *safe* vitamin preparation which contains sufficient folic acid to prevent folic acid deficiency. The prior art is replete with examples of vitamin preparations which either contain insufficient amounts of folic acid to insure prevention of folic acid deficiency or which have so much folic acid that the danger of masking of vitamin $B_{12}$ deficiency is present.

It appears to petitioner that the decision of obviousness within the meaning of section 103 by the Court below could be considered to imply that the companies manufacturing the numerous folic-acid-containing products in the prior art have obviously known how to modify their formulations by a simple change in formulation to make them safe but rather they have preferred to market dangerous products and accompany those products with warning labels warning of the dangers, or alternatively have preferred to market products which have such an insufficient amount of folic acid that they do not insure prevention of folic acid deficiency. Petitioner would prefer to believe that his safe and effective preparation is unobvious to persons skilled in the art rather than to infer that the drug industry has such little concern for the risks of sickness and death associated with the products which it distributes.

It is believed that the decision of the United States Court of Customs and Patent Appeals is clearly at variance with the standards set forth by the United States Supreme Court in *Graham v. John Deere Co.*, 383 U.S. 1 at 17, 148 USPQ 459 at 467 (1966):

> "Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved Against this background, the obviousness or non-obviousness of the subject matter is determined. Such secondary considerations as commercial success, long-

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> felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or non-obviousness, these inquiries may have relevancy."

It is submitted that the United States Court of Customs and Patent Appeals has an obligation to consider the improved results obtained by the petitioner's preparation as compared to the preparations in the prior art. The evidence of improved safety submitted by petitioner in the Patent and Trademark Office should have been considered in determining the question of patentability under Section 103.

The large number of products presently marketed which are either dangerous or ineffective in regard to the folic acid content are believed to be persuasive evidence which needs to be considered. It is apparent to petitioner that he is the first and only advocate of a formulation of the type disclosed in his patent application. Not one example has been put forth by the Patent and Trademark Office of another oral folic-acid-containing product which overcomes the double edged problem of too much folic acid causing masking or too little folic acid allowing folic acid deficiency to occur. The fact that the pharmaceutical industry continues to manufacture products which are either inadequate or dangerous should have considerable relevance to the question of obviousness.

An affidavit of Christian Jansen filed in the Patent and Trademark Office states as follows:

> "7. I have monitored and extensively studied problems of anemia at Marion County General Hospital on 53 patients, most of whom were pernicious anemia patients; and the case histories of a few of these patients are attached as Exhibits B-0 to B-7;"

> "9. I have never observed a case, nor am I aware of any case, in which the compositions of my invention have not been fully safe and fully effective in the treatment of either vitamin $B_{12}$ deficiency anemia or folic acid deficiency or both;"
>
> "12. I have observed many examples, such as those of the attached Exhibits, in which compositions of my invention have been used with complete safety and effectiveness in humans in preventing or curing anemia caused by either folic acid deficiency or vitamin $B_{12}$ deficiency."
>
> "13. I have directed research related to and extensively studied problems of anemia on at least fifty patients additional to those referred to in paragraph 7; and the case histories of a few of these patients are attached as Exhibits B-8 to B-13." (R-40, 41)

It is believed that this affidavit evidence should have been considered by the Patent and Trademark Office and by the United States Court of Customs and Patent Appeals. It is further believed that if this evidence had been properly considered along with the other evidence of record, that a conclusion that the claimed invention was unobvious would have been drawn.

In *Graham v. John Deere Co.*, 383 U.S. at 12, 148 USPQ at 464, this Court reaffirmed its adherence to the formulation of general conditions of patentability which this Court made in 1850 in *Hotchkiss v. Greenwood*, 11 How. 248, and stated:

> "In practice, Hotchkiss has required a comparison between the subject matter of the patent, or patent application, and the background skill of the calling. It has been from this comparison that patentability was in each case determined."

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This Court in *Graham,* 383 U.S. at 18, 148 USPQ at 467, made reference to a law review article, *Subtests of "Non-obviousness,* 112 U. Pa. L. Rev. 1169 (1964). This article treats various approaches to determinations of obviousness and states, p. 1172:

> "The driving force behind innovation is the need for the improvement of existing technology. A defect in a product or process spurs the businessman to deploy resources for discovering a solution. High production costs, undesirable side effects from the use of a product, or a limited period of usefulness are typical of defects which will stimulate research. Existence of the defect creates a demand for its correction, and it is reasonable to infer that the defect would not persist were the solution "obvious."

Petitioner presented evidence in the Patent and Trademark Office of clinical tests proving the safety of his claimed invention with the very individuals who had demonstrated difficulty in absorbing vitamin $B_{12}$ and who would be expected to have developed permanent neurological damage or died if they merely took a product of the prior art. The Board of Appeals of the Patent Office refused to consider this evidence as affecting the question of obviousness, and the United States Court of Customs and Patent Appeals followed suit. It is submitted that this type of evidence must be considered to properly evaluate patentability under the requirements of the United States Constitution and under the requirements of 35 U.S.C. § 103.

## CONCLUSION

It is respectfully submitted that Certiorari should be granted as to each of the questions presented herein for review. The Court below made a fundamental error in not considering the evidence of improved safety presented to the Patent and Trademark Office. It is inconsistent with the Constitutional and statutory standards and inconsistent with the decisions of this Court to ignore evidence of significantly improved results obtained by a novel invention in making a determination of patentability. The Court of Customs and Patent Appeals erred in its determination of patentability and obviousness under 35 U.S.C. § 103. And further, if the decision below is left standing, it would be detrimental to the patent system and detrimental to the goal of promoting the *progress* of the useful arts for which the patent system owes its existence.

The grant of this Petition for Writ of Certiorari is believed to be fully warranted.

Respectfully submitted,

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## CERTIFICATE OF SERVICE

I, John Cameron McNett, counsel for Petitioner, hereby certify that I have served nine copies of the foregoing Petition for Writ of Certiorari by depositing three copies of the same in the United States Mail, properly stamped and addressed, to each of the following:

C. Marshall Dann
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Solicitor General
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This twentieth day of February, 1976.

John Cameron McNett

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